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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/993,234	11/19/2001	Avi J. Ashkenazi	P1007PID1	1337

9157 7590 12/14/2004

GENENTECH, INC.  
1 DNA WAY  
SOUTH SAN FRANCISCO, CA 94080

EXAMINER

NICKOL, GARY B

ART UNIT PAPER NUMBER

1642

DATE MAILED: 12/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>		<b>Applicant(s)</b>	
	09/993,234		ASHKENAZI, AVI J.	
	<b>Examiner</b>		<b>Art Unit</b>	
	Gary B. Nickol Ph.D.		1642	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on 07 April 2004.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 34-39 and 46-94 is/are pending in the application.
- 4a) Of the above claim(s) 35 and 46-94 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 34, 36-39 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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Re: Ashkenazi *et al.*

Date of priority: 09-23-1996

***Response to Amendment***

In response to correcting sequence errors, the amendment filed 04-07-2004 (in response to the Office Action of 10-07-2003) is acknowledged and has been entered.

Claims 34-39, and 46-94 are pending.

Claims 35, 46-94 have been withdrawn from further consideration by the examiner under 37 CFR 1.142(b) as being drawn to non-elected species.

Claims 34, 36-39 are currently under consideration.

**The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.**

**Restriction Requirement:**

Applicants disagree with the withdrawal of claims 91-94. Applicants argue that claim 91 and dependents thereof are encompassed by the elected species (Applicant's previously elected the species of DNA encoding amino acids 25-198 of SEQ ID NO:6—see response filed 7-17-2003, page 2). This is not found persuasive. To be more specific, claims drawn to non-elected species were withdrawn due to the presence of prior art on the elected species (see MPEP

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803.02) . Further, claim 91 does not specifically require the search of the elected species of DNA encoding amino acids 25-198. Thus, claims 35, and 46-94 are withdrawn as drawn to non-elected species.

**Priority:**

Applicants appear to request clarification regarding the Examiner's priority date of 09-23-06 afforded to the instant application. As set forth previously, a review of the parent applications (08/828,683; 08/625,328; 08/710,802) only revealed priority to application No. 08/710,802 filed 09/23/1996. To be more specific, the currently claimed subject matter (nucleic acids encoding SEQ ID NO:6) appeared to only find support in application No. 08/710,802 filed 09/23/1996. In their response applicants have not provided objective evidence to the contrary in order to establish that the claimed subject matter was disclosed in any of the earlier filed provisional applications. Thus, it is maintained that the priority date of the instant application is 09-23-06.

**Information Disclosure Statement:**

As set forth previously, references 210-233, and 235 were improperly cited because they lack publication dates. See 37 CFR 1.98 (b) (5). Applicants argue (page 13) that the Office is taking an "inconsistent position" on the matter because these same references were previously considered and issued on the parent application, now US Patent No. 6,469,144. This argument has been considered and is found persuasive. The examiner will sign and consider the references as applicants have requested. In the event that this application should issue as a patent, it is

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requested that applicants permit the Examiner to edit the references on the 1449 form so as to indicate their dates of publication.

**Rejections Maintained:**

Claim 34 remains rejected under 35 USC 112, first paragraph, as the specification does not contain a written description of the claimed invention. The limitation of an isolated nucleic acid encoding Apo-3 polypeptide comprising amino acid residues **25-417** has no clear support in the specification and the claims as originally filed. Applicants argue (Response, page 14) that support can be found on page 65, lines 28-34 and figure 4 of the instant application. This argument has been considered but is not found persuasive. While the specification provides a generic disclosure for certain domains of SEQ ID NO:6, there is no clear support for the species of DNA encoding residues 25-417 of SEQ ID NO:6. Thus, this would appear to encompass the incorporation of new matter into the disclosure. Thus, applicant's arguments have not been found persuasive and the rejection is maintained.

Claims 34, 36-39 remain rejected under 35 U.S.C. 102(e) as being anticipated by Yu *et al.* (US Patent No. 6,153,402; *earliest priority date is March 12, 1996*; IDS #25 and #26) for the reasons of record.

Applicants argue that the first priority application of Yu *et al.* "disclosed the sequence only of DR3-V1;" and that the second sequence "DR3" was disclosed for the first time in the later filed provisional application of Yu *et al.* This argument has been considered but is not found persuasive as applicants have not provided any clear evidence that the disclosure of DR3 or DR3-VI does not anticipate the currently claimed subject matter. Mere recitation of "DR3"

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and “DR3-VI” only represent laboratory designations and do not serve to effectively compare the prior art to the pending claimed subject matter.

Applicants further argue that disclosure of DR3-V1 (DDCR) in the first priority application of Yu *et al.* is the “only experimental information in the specification” and that “all of the remaining ‘examples’ in the first priority application of Yu *et al.* are in fact prophetic. Applicant’s thus submit (page 16) that the first priority application of Yu *et al.* is non-enabling. This argument has been considered but is not found persuasive. It’s not clear how applicants can argue that the prior art is both (1) non-anticipatory and (2) seemingly anticipatory- but non-enabled. As set forth previously, Yu *et al.* clearly taught an isolated nucleic acid encoding amino acid residues 25-198 via the previously attached sequence comparison and also on page 67 of US Provisional 60/013,285 beginning at amino acid position No. 36. Thus, applicant’s arguments have not been found persuasive and the rejection is maintained.

**Rejection Withdrawn:**

The rejection of Claims 34, and 36-39 under 35 U.S.C. 112, first paragraph (written description) is withdrawn. Applicants have argued that the specification expressly defines “biologically active variants” on page 19, lines 6-11. In view of the limited definition, this rejection is withdrawn.

No claim is allowed.

**All other rejections and or objections are withdrawn in view of applicant's amendments and arguments there to.**

***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

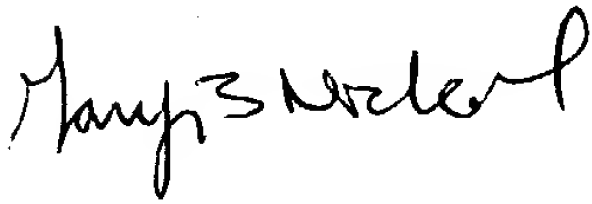
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary B. Nickol Ph.D. whose telephone number is 571-272-0835. The examiner can normally be reached on M-Th, 8:30-5:30; alternate Fri., 8:30-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Gary B. Nickol Ph.D.  
Primary Examiner  
Art Unit 1642

GBN

  
**GARY NICKOL**  
**PRIMARY EXAMINER**